

### **Remarks/Arguments**

Applicants have received and carefully reviewed the Office Action of the Examiner mailed April 1, 2009 and Advisory Action mailed July 20, 2009. Currently, claims 11-20 remain pending. Claims 11-20 have been rejected. Claims 11, 19, and 20 have been amended to clarify the relationships among the elements. Favorable consideration of the following remarks is respectfully requested.

### **Claim Rejections – 35 USC § 103**

Claims 11-17, 19, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Frid et al. (U.S. Patent No. 6,159,228), hereinafter Frid, in view of Roberts et al. (U.S. Patent No. 5,984,964), hereinafter Roberts. After careful review, Applicant must respectfully traverse this rejection.

“All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). (MPEP § 2143.03). As discussed previously and acknowledged by the Examiner, nowhere does Frid appear to disclose “a second position in which the distal end of the inner shaft engages the distal end of the outer shaft”.

Nowhere does Roberts appear to remedy the acknowledged shortcomings of Frid. The Examiner asserts that “Roberts teaches a device similar to that of Frid, but including a second position wherein the inner shaft 12 distal end engages the outer shaft distal end so that the user can be certain that the stent has been released from the outer sheath member” with reference to Fig. 1A of Roberts.

It would appear that the Examiner is equating the handles 12 and 25 of Roberts with the inner and outer shafts of the pending claims and asserting that reduced diameter distal end of handle (12), larger than the immediately adjacent proximal end of catheter (4), can advance further distally within handle (25), said handle (25) being attached to sheath (24), than depicted in Fig. 1A and thus to be stopped from further advance by contact with the distal end of handle (25) and that this action would correspond to sliding the inner shaft of claims 11, 19, and 20 within the outer shaft lumen of the pending

claims. Applicant has amended claims 11, 19, and 20 to clarify that the outer shaft has a lumen and that the inner shaft is disposed within that lumen in both the first and second positions. The available travel within the handle (25) of Roberts appears to be insufficient to allow the stent of Roberts to reside within the sheath in the first position and to lie outside the sheath in a supposed second position in which the distal end of handle (12) is fully in contact with the distal interior of handle (25). As will be seen in Fig. 1, the distal end of handle (12) of Roberts does not appear to lie within a lumen of handle (25) in a first position in which the distal end of the inner shaft is positioned within the lumen of the outer shaft and spaced from the distal end of the outer shaft and in which a treatment element mounting region is covered by the distal end of the sheath as found in amended claims 11, 19, and 20.

As noted before, the device of Roberts does not appear to disclose "a distal end configured to engage the outer shaft distal end" corresponding to a configuration in which the distal end of handle (12) is capable of contacting the distal end of the lumen of handle (25) for the reason that the proximal flanges of the handles would make contact well before the distal end of handle (12) contacts the distal end of the lumen of handle (25) as depicted in Fig. 1A. Thus Roberts does not appear to teach a deployment system having either a first position or a second position as those positions are currently claimed.

In the Response to Arguments, the Examiner has asserted that the drawings of Roberts are not to scale which assertion does not appear to be supported by the disclosure of Roberts. The absolute scale of drawing 1A was not in question in the response to the final Office Action and the dimensions were not being compared to those of the pending application as was the case in *Hockerson-Halberstadt, Inc. v. Avia Group Int'l*, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000), cited by the Examiner, but rather the functional relative linear displacements available to various components within individual figures of Roberts were compared as they would be understood by one of skill in the art.

"However, the description of the article pictured can be relied on, in combination with the drawings, for what they would reasonably teach one of ordinary skill in the art. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977)."

The description of Fig. 1 at columns 4-5 does provide linear dimensions, both absolute and relative, identified in Fig. 1 as L<sub>1</sub>-L<sub>9</sub>, and some measures of the diameters of

components. At col. 4, line 66 to col. 5, line 1, Roberts discloses that the “distance between the handle 25 on the sheath, and handle 12, on the catheter, corresponds approximately to the length of the compacted stent” which is  $L_3$ .  $L_3$  is said to be about 15 cm at column 4, line 19. One of ordinary skill in the art would appreciate that the distance between the handles in Fig. 1 is significantly greater than the length of any possible lumen within handle (25) as depicted for the reason that the scale in the two halves of the device of Fig. 1 is depicted as at least approximately the same in both segments of the illustrated device as indicated by the constant diameters of the catheter and sheath across the gap. Accordingly, movement between the configuration of Fig. 1 and that of Fig. 1A requires a displacement greater than the length of handle (25) and so greater than the length of any lumen thereof.

Frid and Roberts, alone or in combination, do not appear to teach a treatment element delivery device having a first position and a second position as described by pending claims 11, 19, and 20. Therefore, for at least this reason, Frid in view of Roberts does not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness and Applicant respectfully requests that the rejections of claims 11, 19 and 20 be withdrawn.

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). (MPEP 2143.03)

Applicant believes that claims 12-17, which depend from nonobvious independent claim 11, are also nonobvious and respectfully requests that the rejections be withdrawn.

Claims 10 and 18 were rejected under 35 U.S.C. 103(a) as being unpatentable over Frid in view of Roberts and DiCaprio et al. (U.S. Patent No. 6,176,843), hereinafter DiCaprio. After careful review, Applicant must respectfully traverse this rejection.

The Examiner's attention is drawn to the fact that claim 10 was canceled in an earlier communication.

The Examiner acknowledges that claim 18 differs from Frid in view of Roberts in calling for a valve for flushing air from the sheath. DiCaprio is said to teach a device for

delivering a stent having a valve 34 that allows air to be forced out of the lumen to prevent the possibility of an air embolism forming. The valve of DiCaprio does not appear to overcome the deficiencies of Frid in view of Roberts as applied to claim 11 as discussed above and thus Frid in view of Roberts and DiCaprio fails to render independent claim 11 obvious for at least the reason that the references alone or in combination do not appear to teach all the claim limitations, as is required to establish a *prima facie* case of obviousness. Applicant believes that claim 18, which depends from nonobvious independent claim 11, is also nonobvious and respectfully requests that the rejection be withdrawn.

In the Response to Arguments, the Examiner states that she “does not necessarily agree” with the assertion that “*Omission of an Element with Retention of the Element’s Function Is an Indicia of Unobviousness*” (MPEP 2144.04, II, B). Applicant notes that the omission of the flexible pusher with retention of the pusher function is an indicia of unobviousness; however it may or may not be absolutely controlling with respect to obviousness of the invention.

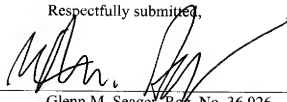
As noted above, the issue raised with respect to Figure 1A is not one of scale, but rather one of relative dimensions within the figure. As disclosed by Roberts, the distal end of handle (12) cannot be said to be “configured to engage the outer shaft distal end”, the distal end of the lumen within handle (25), for the simple reason that the proximal flanges of the two handles would come into contact first. Although this observation is still true, this issue is now believed to be immaterial in view of the amendments to the claims which require that the inner shaft distal end be within the lumen of the outer shaft in the first position and this is not the case in the dimensioned Fig. 1 of Roberts.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Reexamination and reconsideration are respectfully requested. Issuance of a Notice of Allowance in due course is anticipated. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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